Notice of Allowability	Application No.	Applicant(s)	
	10/537,642	SETTE ET AL.	
	Examiner	Art Unit	
	LAKIA TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the Request for Continued Examination filed on 10/14/10*.

2. ☒ The allowed claim(s) is/are *45-65 and 70-77*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 9/22/10
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *4/21/11* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/VANESSA L FORD/
Primary Examiner, Art Unit 1645

EXAMINER'S AMENDMENT

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 14, 2010 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on September 22, 2010 is in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto.

3. This office action is responsive to Applicant's response filed October 14, 2010. In view of Applicant's response, all rejections of record are withdrawn. Claims 45-65 and 70-77 are pending and under examination.

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Glenn Ladwig on April 21, 2011.

Rejoinder

5. The restriction requirement mailed on February 5, 2008 included claims 1-44. Applicant's response to the restriction requirement filed on August 5, 2008 canceled all the pending claims (1-44) and added new claims 45-65. Claim 65 is drawn to a method of making. Since applicant had received an action on the merits for the originally presented invention (the product), this invention had been constructively elected by original presentation for prosecution on the merits. Therefore, Applicant's elected invention was claims 45-64 and accordingly, claim 65 (drawn to a process of making) was withdrawn from consideration as being directed to a non-elected invention on December 5, 2008. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 45-64 and 70-77 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claim 65, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, is hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on February 5, 2008 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any

claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 45-65 and 70-77 are being examined in this application and are allowed.

6. The application has been amended as follows:

In the claims:

Claim 45 (currently amended): An isolated or purified polynucleotide: a) encoding a polypeptide comprising SEQ ID NO: 1; b) encoding a Human Leukocyte Antigen (HLA) binding fragment of SEQ ID NO: 1, wherein said HLA binding fragment comprises ~~an~~ the amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile- Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr

(SEQ ID NO:37); or c) that is complementary along the full length of said polynucleotide of a) or b).

Claim 50 (currently amended): A vector comprising a promoter operably linked to a polynucleotide: a) encoding a polypeptide comprising SEQ ID NO: 1; b) encoding a Human Leukocyte Antigen (HLA) binding fragment of SEQ ID NO: 1, wherein said HLA binding fragment comprises ~~an~~ the amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile- Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37); or c) that is complementary along the full length of said polynucleotide of a) or b).

Claim 55 (currently amended): An isolated transformed host cell comprising a polynucleotide: a) encoding a polypeptide comprising SEQ ID NO: 1; b) encoding a Human Leukocyte Antigen (HLA) binding fragment of SEQ [D NO: 1, wherein said HLA binding fragment comprises ~~an~~ the amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-

Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile- Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37); or c) that is complementary along the full length of said polynucleotide of a) or b).

Claim 60 (currently amended): An isolated transformed host cell according to claim 55, wherein said polynucleotide is a vector comprising a promoter operably linked to a polynucleotide: a) encoding a polypeptide comprising SEQ ID NO: 1; b) encoding a Human Leukocyte Antigen (HLA) binding fragment of SEQ [D NO: 1, wherein said HLA binding fragment comprises ~~an~~ the amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile- Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37); or c) that is complementary along the full length of said polynucleotide of a) or b).

Claim 74 (currently amended): The isolated or purified polynucleotide according to claim 45, wherein said polynucleotide encodes said HLA binding fragment,

and wherein said HLA binding fragment consists of ~~an~~ the amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile- Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37).

Claim 75 (currently amended): The vector according to claim 50, wherein said polynucleotide encodes said HLA binding fragment, and wherein said HLA binding fragment consists of ~~an~~ the amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile- Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37).

Claim 76 (currently amended): The isolated transformed host cell according to claim 55, wherein said polynucleotide encodes said HLA binding fragment, and

wherein said HLA binding fragment consists of ~~an~~ the amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile- Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37).

Claim 77 (currently amended): The isolated transformed host cell according to claim 60, wherein said polynucleotide encodes said HLA binding fragment, and wherein said HLA binding fragment consists of ~~an~~ the amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile- Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37).

Examiner's Reasons for Allowance

7. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggest an isolated or purified polynucleotide, vector or transformed host cell comprising: a) encoding a polypeptide comprising SEQ ID NO: 1; b) encoding a Human Leukocyte Antigen (HLA) binding fragment of SEQ ID NO: 1, wherein said HLA binding fragment comprises the amino acid sequence selected from Lys-Thr-Asn-Lys-Trp-Glu-Asp-Ile-Tyr (SEQ ID NO:28), Lys-Ser-Ile-Tyr-Ile-Phe-Tyr-Thr-Tyr (SEQ ID NO:29), Gly-Thr-Phe-Thr-Phe-Gln-Asn-Met-Tyr (SEQ ID NO:30), Tyr-Phe-Glu-Cys-Ile-Met-Lys-Leu-Tyr (SEQ ID NO:32), Val-Tyr-Glu-Gly-Lys-Leu-Lys-Lys-Tyr (SEQ ID NO:33), Val-Val-Asp-Leu-Phe-Cys-Gly-Val-Gly-Tyr (SEQ ID NO:34), Phe-Ser-Ser-Ile- Asn-Thr-Tyr-Asp-Tyr (SEQ ID NO:35), Val-Ser-Asn-Val-Glu-Asp-Ser-Asn-Tyr (SEQ ID NO:36), or Asn-Ser-Asn-Tyr-Asn-Lys-Lys-Leu-Tyr (SEQ ID NO:37); or c) that is complementary along the full length of said polynucleotide of a) or b).

8. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Status of Claims

9. Claims 45-65 and 70-77 are allowed.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
4/21/11

/VANESSA L FORD/
Primary Examiner, Art Unit 1645